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10/521,103	02/14/2005	Steven Gareth Griffiths	VA/H-32534A	5430

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ONE HEALTH PLAZA 104/3
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EXAMINER	
GRASER, JENNIFER E	
ART UNIT	**PAPER NUMBER**
1645	
MAIL DATE	**DELIVERY MODE**
02/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,103	GRIFFITHS ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-8,17,31-33 and 35-39* is/are pending in the application.

4a) Of the above claim(s) *39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-8,17,31-33 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Acknowledgment and entry of the Amendment submitted on 11/2/07 is made. Claims 3-8, 17, 31-33 and 35-39 are currently pending. New claim 39 is withdrawn as being drawn to a non-elected invention (see 'Elections/Restrictions' below).

Election/Restrictions

1. Newly submitted claim 39 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

New claim 39 is directed to an adjuvant composition. The instant claims are drawn to vaccines and methods of prevention using the claimed nucleic acid as the active antigen, not as an enhancer (adjuvant) of a hapten or antigen. The use of the nucleic acid as an adjuvant was not previously searched. Applicants are entitled to the search of only one invention per application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 39 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112-2nd paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3-8, 17, 31-33 and 35-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is vague and indefinite due to the phrase "a sequence having 95% homology thereto, wherein the polypeptide is an Arthrobacter hsp70 protein". There is no functional requirement for the homologous sequence. It is unclear what defines a 'Arthrobacter hsp70 protein'. The claim does not require the sequence to possess a specific function thereby making it unclear what structures would fall under the metes and bounds of the claim. Sequences with 95% homology are not necessarily "Arthrobacter hsp 70 proteins'. What functionality is encompassed by a 'Arthrobacter hsp70 protein"? Clarification and correction is requested. Additionally, support for amino acid residues 162-365 of SEQ ID NO: 2 in part (b) of the claim could be found on page 5 of the instant specification, e.g., Domain II fragment. However, written support could not be found for nucleotides 291-2956 of SEQ ID NO: 1. Is the sequence which encodes amino acids 162-365 of SEQ ID NO: 2? If so, there would be *ispsis verbis* support. If not, there would be a possible 112, first paragraph new matter rejection. Clarification is required.

Claim Rejections - 35 USC § 112-Enablement

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 3-8, 17, 31-33 and 35-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "an isolated polynucleotide comprising the nucleic acid sequence set forth in SEQ ID NO: 1', 'an isolated polynucleotide which the amino acid sequence set forth in SEQ ID NO: 2 or SEQ ID NO: 2 amino acids 162 to 365, does ***not*** reasonably provide enablement for 'an isolated nucleic acid sequence encoding [any] Arthrobacter hsp70 protein which is 95% homologous to SEQ ID NO: 2. Vaccine compositions comprising any of the claimed expression vectors are not enabled, nor are methods of preventing *any* disease in a fish. The methods of newly submitted claims 35-37 are also not enabled.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The breadth of the instant claims is drawn to polynucleotides that are not specified in the sequence disclosure. The specification states that substitutions, additions, or deletions may be made to the defined sequences; however, the specification provides no guidance as to what nucleic acids may be changed without causing a detrimental effect to the protein to be produced. Further, it is unpredictable as to which nucleotides/amino acids could be removed and which could be added. While it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of success are limited. Other positions are critical to the protein's structure/function relationship, e.g., such as various positions or regions

directly involved in binding, catalysis in providing the correct three-dimensional spatial orientation of binding and catalytic sites. These regions can tolerate only very little or no substitutions. To start with the DNA sequence first, this requires even more work on the part of the skilled artisan.

The instant claims are drawn to nucleic acids comprising a sequence with a given percent similarity to a nucleic acid which encodes a protein. Selective point mutation to one key residue could eliminate the function of the polypeptide. If the range of decreased binding ability after single point mutation of a protein antigen varies, one could expect point mutations in the protein antigen to cause varying degrees of loss of protection/function, depending on the relative importance to the binding interaction of the altered residue. Alternatively, the combined effects of multiple changes in an antigenic determinant could again result in loss of function. A protein having multiple antigenic sites, multiple point mutations, or accumulated point mutations at key residues could create a new antigen that is precipitously or progressively unrecognizable by any of the antibodies in the polyclonal pool. As stated above, Applicants have not shown which nucleotides may be changed without causing a detrimental effect to the protein in which it encodes. The claims allow for as great as 5% variation without requiring a function, e.g., the limitation that the claim is an Arthrobacter hsp70 protein is not a function. Applicants have provide no guidance to enable one of ordinary skill in the art how to determine, without undue experimentation, the effects of different nucleotide substitutions and the nature and extent of the changes that can be made. It is expensive and time consuming to make amino acid substitutions at more than one

position, in a particular region of the protein, in view of the many fold possibilities for change in structure and the uncertainty as to what utility will be possessed. See Mikayama et al. (Nov.1993. Proc.Natl.Acad.Sci. USA, vol. 90 : 10056-10060) which teaches that the three-dimensional structure of molecules is important for their biological function and even a single amino acid difference may account for markedly different biological activities. Rudinger et al. (June 1976. Peptide Hormones. Biol.Council. pages 5-7) also teaches that amino acids owe their 'significance' to their inclusion in a pattern which is directly involved in recognition by, and binding to, the receptor and the significance of the particular amino acids and sequences for different amino acids cannot be predicted *a priori*, but must be determined from case to case by painstaking experimental study._Given the lack of guidance contained in the specification regarding acceptable nucleotide substitutions, additions or deletions, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.
The specification also does not enable vaccine compositions comprising DNA expression vectors comprising SEQ ID NO:1, fragments thereof which encode amino acids 162-365 of Hsp70 or a sequence having at least 95% homology thereto or a sequence which under stringent conditions hybridizes with the sequence of SEQ ID NO:1, nor do they enable a method of preventing ***any*** disease in a fish comprising administering the aforementioned vaccines.

The instant specification at pages 24-25, Example 4, teaches that Atlantic salmon can be vaccinated intramuscularly with DNA expression vector/plasmids pUKrsxHSP70-ipnVP2 and pUKrsxHSP70-ipnVP3. The fish are challenged 4-6 weeks

later by exposure to virulent IPNV (infectious pancreatic necrosis virus) and results indicate that "all of the nucleic acid vaccines based on the VP2 sequence of IPNV are protective against challenge by the virus, including the hsp70-VP2 fusion. The results do not state that the hsp70-VPN3 vaccines were successful. The results indicate that the VP2 sequence achieved protection against virulent IPNV, but are silent as to whether VP3 sequence has the same ability. Accordingly, only vaccines comprising pUKrsxHSP70-ipnVP2 and methods of protecting against disease caused by infection with IPNV (infectious pancreatic necrosis virus) are enabled. The specification does not provide any other working examples for prevention or protection against any other disease in fish (including Infectious Salmon Anaemia Virus, salmonid rickettsial septicaemia or bacterial kidney disease as recited in new claims 35-37), nor does it provide results with the use of any other DNA expression vectors, including solely an expression vector comprising comprising SEQ ID NO:1, fragments thereof which encode amino acids 162-365 of Hsp70 or a sequence having at least 95% homology thereto or a sequence which under stringent conditions hybridizes with the sequence of SEQ ID NO:1. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim

certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." The vaccine art is highly unpredictable and therefore actual results from challenge experiments are necessary to enable vaccines and methods of prevention/protection. When considering a bacterial antigen as a vaccine candidate, three major considerations must be raised (1) the antigen must be conserved among strains of the bacterial species whose disease one wishes to prevent; (2) it must generate protective antibody such that the antibody to the antigen prevents disease; and (3) it must be a good immunogen such that protective antibodies are elicited in the population at risk and that these antibodies persist for sufficient time to provide protection throughout the risk period (Murphy et al. Pediatr. Infect. Dis. J. 1989. 8: S66-S68). Even when an antigen meets these three considerations, further testing often indicates that the antigen will not be effective as a vaccine. For example, Murphy et al. Pediatr. Infect. Dis. J. 1989. 8: S66-S68, teach that P6 is an important vaccine candidate based on these considerations, but Yamanaka et al (J. Pediatrics. 1993. 122(2): 212-218) later demonstrated that the population at most risk did recognize P6 as an antigen. The instant specification fails to demonstrate that the claimed DNA structures meet any of the three considerations known in the art to be important when considering a bacterial antigen as a vaccine candidate. Without specific guidance from the specification, it would take undue experimentation for those skilled in the art to make and/or use the claimed invention. Applicants should provide additional evidence, such as challenge experiments, to demonstrate these structures' ability as

vaccines. There are no experiments which demonstrate that any of the claimed constructs could prevent ***any*** disease in fish (more specifically including Infectious Salmon Anaemia Virus, salmonid rickettsial septicaemia or bacterial kidney disease as recited in new claims 35-37).

Given the lack of guidance contained in the specification, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

Response to Applicants' Arguments:

Applicants argue that the amendment to include that the variant sequences (95% homology) are Arthrobacter hsp70 proteins overcome the enablement rejection have been fully and carefully considered but are not deemed persuasive. There is no functional requirement for the homologous sequence. It is unclear what defines a 'Arthrobacter hsp70 protein'. The claim does not require the sequence to possess a specific function thereby making it unclear what structures would fall under the metes and bounds of the claim. Sequences with 95% homology are not necessarily "Arthrobacter hsp 70 proteins'. What functionality is encompassed by a 'Arthrobacter hsp70 protein"? This is not, for example, a specific enzymatic function which is easily assayed. Clarification and correction is requested.

With respect to the vaccines and methods of prevention, Applicants have argued that 'working' examples are not required. They argue that is within one of skill in the art to discover constructs which would have the ability to prevent any disease in fish (and, including Infectious Salmon Anaemia Virus, salmonid rickettsial septicaemia or bacterial kidney disease as recited in new claims 35-37). This has been fully and carefully

considered but is not deemed persuasive. The test for whether an invention is enabled takes into account whether a disclosure would require undue experimentation and includes: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims. The bacterial vaccine art is highly unpredictable. As stated above, when it comes to evaluating methods of *prevention* of disease and *vaccines* in a highly unpredictable art, such as bacterial vaccine, the standard is high and specific examples are needed to support enablement. When considering a bacterial antigen as a vaccine candidate, three major considerations must be raised (1) the antigen must be conserved among strains of the bacterial species whose disease one wishes to prevent; (2) it must generate protective antibody such that the antibody to the antigen prevents disease; and (3) it must be a good immunogen such that protective antibodies are elicited in the population at risk and that these antibodies persist for sufficient time to provide protection throughout the risk period (Murphy et al. Pediatr. Infect. Dis. J. 1989. 8: S66-S68). Even when an antigen meets these three considerations, further testing often indicates that the antigen will not be effective as a vaccine. For example, Murphy et al. Pediatr. Infect. Dis. J. 1989. 8: S66-S68, teach that P6 is an important vaccine candidate based on these considerations, but Yamanaka et al (J. Pediatrics. 1993. 122(2): 212-218) later demonstrated that the population at most risk did recognize P6 as an antigen. The instant specification fails to demonstrate that the claimed DNA

structures meet any of the three considerations known in the art to be important when considering a bacterial antigen as a vaccine candidate. Without specific guidance from the specification, it would take undue experimentation for those skilled in the art to make and/or use the claimed invention. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention."

The instant specification at pages 24-25, Example 4, teaches that Atlantic salmon can be vaccinated intramuscularly with DNA expression vector/plasmids pUKrsxHSP70-ipnVP2 and pUKrsxHSP70-ipnVP3. The fish are challenged 4-6 weeks later by exposure to virulent IPNV (infectious pancreatic necrosis virus) and results indicate that "all of the nucleic acid vaccines based on the VP2 sequence of IPNV are protective against challenge by the virus, including the hsp70-VP2 fusion. The results do not state that the hsp70-VPN3 vaccines were successful. The results indicate that the VP2 sequence achieved protection against virulent IPNV, but are silent as to

whether VP3 sequence has the same ability. Accordingly, only vaccines comprising pUKrsxHSP70-ipnVP2 and methods of protecting against disease caused by infection with IPNV (infectious pancreatic necrosis virus) are enabled. This does not mean that VP2 is necessary; however, it also does not support whether VP3 possesses the same ability.

Claim Rejections - 35 USC § 112-Written Description

6. Claims 3-8, 17, 31-33 and 35-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID NO: 1 and equivalent degenerative codon sequences thereof and therefore the written description is not commensurate in scope with the claims which encompass variants, derivatives, fragments and analogs from the full-length sequence, from hybrids or from epitope-bearing portions.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. With the exception of SEQ ID NO: 1, the skilled artisan cannot envision the detailed structure of the encompassed polynucleotides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016.

Furthermore, In The Reagents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise

definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

No disclosure, beyond the mere mention of allelic variants is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore, only "an isolated polynucleotide comprising the nucleic acid sequence set forth in SEQ ID NO: 1', 'an isolated polynucleotide which encodes the amino acid sequence set forth in SEQ ID NO: 2 or SEQ ID NO: 2 amino acids 162 to 365', but not the full breadth of the claims meets the written description provisions of 35 USC 112, first paragraph.

Response to Applicants' Arguments:

Applicants argue that their amendments overcome the rejection of record. This has been fully and carefully considered but is not deemed persuasive. As stated above, Claim 3 is vague and indefinite due to the phrase "a sequence having 95% homology thereto, wherein the polypeptide is an Arthrobacter hsp70 protein". There is no functional requirement for the homologous sequence. It is unclear what defines a 'Arthrobacter hsp70 protein'. The claim does not require the sequence to possess a specific function thereby making it unclear what structures would fall under the metes and bounds of the claim. Sequences with 95% homology are not necessarily "Arthrobacter hsp 70 proteins'. What functionality is encompassed by a 'Arthrobacter

hsp70 protein"? This is not, for example, a specific enzymatic function which is easily assayed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Shanon Foley, can be reached on (571) 272-0898.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

11/24/08

Jennifer Graser
Primary Examiner
Art Unit 1645